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| APPLICATION NO. 087765,837 | FILING DATE 09/07/99 | FIRST NAMED INVENTOR LAUB | ATTORNEY DOCKET NO. VERMILION 151A |
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HM12/0922

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| EXAMINER CLEMENS, R |
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| ART UNIT 1544 | PAPER NUMBER 10 |
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09/22/00

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | | |
|------------------------------|-------------------------------|-----------------------------|--|
| Office Action Summary | Application No. 08/765,837 | Applicant(s) LAUB ET AL. | |
| | Examiner Karen Clemens | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-43 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 31-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☒ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|--|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION
Election / Restriction

The Examiner of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Karen Clemens in Art Unit 1644, Technology Center 1600 ((703) 308-8365).

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Applicant's election of Group I, claims 31-36, 38, 39, 41 and 42 in Paper No. 7 is acknowledged. However, upon reconsideration the restriction requirement has been modified as set forth below.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 31-36 and 39 drawn to a polypeptide and a pharmaceutical composition classified in class 530, subclass 383, and class 424, subclass 185.1.
- II Claims 37 and 39 drawn to an antibody as inhibitor of factor VIII and a pharmaceutical composition , classified in class 530, subclass 387.1 and class 424, subclass 130.1.

- III. Claims 38 and 39 drawn to an anti-idiotypic antibody as anti-inhibitor of factor VIII and a pharmaceutical composition classified in class 530, subclass 387.1 and class 424, subclass 131.1.
- IV. Claim 40 drawn to a diagnostic and/or purification device comprising a polypeptide, classified in class 530, subclass 344.
- V. Claim 40 drawn to a diagnostic and/or purification device comprising an inhibitor of factor VIII, classified in class 530, subclass 344.
- VI. Claim 40 drawn to a diagnostic and/or purification device comprising an anti-inhibitor of factor VIII, classified in class 530, subclass 344.
- VII. Claim 41 drawn to a method for therapeutic treatment/prevention administering a polypeptide classified in class 514, subclass 12.
- VIII. Claim 41 drawn to a method for therapeutic treatment/prevention administering an antibody classified in class 424, subclass 130.1.
- IX. Claim 41 drawn to a method for therapeutic treatment/prevention administering an anti-idiotypic antibody as classified in class 424, subclass 131.1.
- X. Claim 42 drawn to a method for obtaining an inhibitor of factor VIII classified in class 436, subclass 518.
- XI. Claim 43 drawn to a method for identifying anti-inhibitors of factor VIII classified in class 436, subclass 518.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions listed in Group I were found to have no special technical feature that defined the contribution over the prior art of Vehar et al. (*Nature* 312:337-42, 1984). Vehar et al. teach the human

factor VIII polypeptide. Therefore the inventions of Group I have been previously described.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and lack unity of invention.

2. The inventions are distinct, each from the other because:

A. Groups I-VI are unique products. They differ with respect to their structures and physicochemical properties and are therefore patentably distinct.

B. Groups I/VII, II/VIII, and III/XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in materially different processes such as in protein binding assays or immunoaffinity purification procedures.

C. Groups VII-XI are different methods. They require different ingredients, process steps and endpoints to achieve different goals. Therefore, they are patentably distinct each from the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

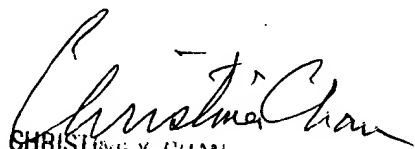
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(l).)

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Clemens whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Karen Clemens, Ph.D.
Patent Examiner
Technology Center 1600
August 22, 2000


CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1800-1644